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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,969	CHEN ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-40 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-12 and 20-22, drawn to an *in vitro* method for diagnosis of pancreatic cancer, said method comprising detecting the presence or amount of a "marker" in a sample, wherein said "marker" comprises at least one polypeptide selected from a group of polypeptides set forth in any of claims 1, 2, and 20-22, classified, for example, in class 435, subclass 7.21, or to said "marker", which cannot be classified because the nature and substance of the "marker" is not sufficiently delineated by the claims to permit classification.

Group II. Claims 13, 14, 33, and 34, drawn to drawn to a method for identifying and/or obtaining a compound that interacts with at least one polypeptide, or inhibits or antagonizes said at least one polypeptide, said method comprising contacting said at least one polypeptide with a compound and detecting the interaction of the polypeptide and the compound, or determining if the activity of said at least one polypeptide is negatively affected upon its contact with the compound, wherein said at least one polypeptide is selected from a group consisting of the polypeptides set forth in any of claims 13, 14, and 33, which cannot be classified because the nature and substance of the compound, nor its activity is specified by the claims to permit classification.

Group III. Claims 15 and 35, drawn to drawn to a method for identifying and/or obtaining a compound that inhibits the expression of at least one polypeptide, said method comprising contacting a host that expresses said at least one polypeptide with a compound and determining if the expression and/or

activity of said at least one polypeptide is negatively affected, wherein said at least one polypeptide is selected from a group consisting of the polypeptides set forth in any of claims 15 and 35, which might be classified, for example, in class 435, subclass 6.

Group IV. Claims 16, 17, 36, and 37, drawn to antibodies or antigen-binding fragments thereof, or a kit comprising said antibodies or antigen-binding fragments thereof, wherein said antibodies and antigen-binding fragments thereof bind at least one polypeptide selected from a group of polypeptides set forth in any of claims 16 and 36, classified, for example, in class 530, subclass 389.1.

Group V. Claims 18 and 38, drawn to a kit comprising one or more nucleic acid molecules encoding a "marker", wherein said "marker" comprises at least one polypeptide selected from a group of polypeptides set forth in any of claims 1 and 20, classified, for example, in class 536, subclass 23.5.

Group VI. Claims 19, 39, and 40, drawn to a kit comprising compounds that activate or inhibit any of the polypeptides of a group of polypeptides set forth in any one of claims 19, 39, and 40, which cannot be classified because the nature and substance of the compounds is not specified in the claims.

Group VII. Claims 19, 39, and 40, drawn to a kit comprising compounds that stimulate or inhibit the expression of any of the polypeptides of a group of polypeptides set forth in any one of claims 19, 39, and 40, which cannot be classified because the nature and substance of the compounds is not specified in the claims.

Group VIII. Claims 23-26, insofar as the claims are drawn to an *in vitro* method for diagnosing pancreatic cancer, said method comprising detecting or

measuring the amount of at least one polypeptide in a sample, wherein said at least one polypeptide is selected from a group consisting of the polypeptides set forth in any of claims 23, 24, and 25, classified, for example, in class 436, subclass 501.

Group IX. Claims 23-26, insofar as the claims are drawn to an *in vitro* method for determining a susceptibility to pancreatic cancer, said method comprising detecting or measuring the amount of at least one polypeptide in a sample, wherein said at least one polypeptide is selected from a group consisting of the polypeptides set forth in any of claims 23, 24, and 25, classified, for example, in class 436, subclass 501.

Group X. Claims 27-32, insofar as the claims are drawn to an *in vitro* method for diagnosing pancreatic cancer, said method comprising detecting or measuring the amount of at least one nucleic acid molecule encoding a "marker" according to claim 23, classified, for example, in class 435, subclass 6.

Note: Claim 23 does not define the "marker" to which claims 27-32 are directed.

Group XI. Claims 27-32, insofar as the claims are drawn to an *in vitro* method for determining a susceptibility to pancreatic cancer, said method comprising detecting or measuring the amount of at least one nucleic acid molecule encoding a "marker" according to claim 23, classified, for example, in class 435, subclass 6.

Note: Claim 23 does not define the "marker" to which claims 27-32 are directed.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and IV-VII are, or include products, whereas the inventions of Groups I-III and VIII-XI are, or include processes.

The inventions of Group I and the inventions of Groups II, III, and VIII-XI are unrelated because the products of Group I are not specifically used or otherwise involved in the processes of Groups II, III, and VIII-XI.

The inventions of Group IV-VII and the inventions of Groups I-III and VIII-XI are unrelated because the products of Group IV-VII are not specifically used or otherwise involved in the processes of Groups I-III and VIII-XI.

The products of the inventions of Groups I and IV-VII are patentably distinct for the following reasons:

The products of the inventions of Group I are "markers", which although described as comprising one or more specifically identified polypeptides, have not been described as comprising any other particular substance or structure; in contrast, the products of Groups IV-VII are kits comprising either antibodies or fragments thereof, nucleic acid molecules, compounds that activate or inhibit the activity of one or more polypeptides, or compounds that stimulate or inhibit the expression of one or more polypeptides. With regard to the products of Groups IV-VII, as will be explained in greater detail in the paragraphs below, antibodies, or fragments thereof, and nucleic acid molecules are patentably distinct; and the compounds to which the claims of Groups VI and VII are directed, which stimulate or inhibit expression of one or more polypeptides, or activate or inhibit the activity of one or more polypeptides are presumably not limited any one class of molecule, and are thus presumed patentably distinct from both the antibodies, or fragments thereof, of the inventions of Group IV and the nucleic acid molecules of the inventions of Group V. Moreover, because the nature and substance of the compounds that activate or inhibit the activity of one or more polypeptides is not specified, the claims are therefore directed to a genus of kits comprising one or more structurally different compounds, each of which shares either the ability to activate or inhibit the activity of one or more specifically identified polypeptides. Notably, inasmuch as the activities of these polypeptides are not known, or have not been described, it is not apparent that there is one or more compound, or one or more classes of compounds that might be used to achieve the activation or inhibition of any one set of these polypeptides. Similarly the nature and substance of

the compounds that stimulate or inhibit the expression of one or more polypeptides is not specified by the claims; therefore, the claims are directed to a genus of kits comprising one or more structurally different compounds, each of which shares either the ability to stimulate or inhibit the expression of one or more specifically identified polypeptides. Again, it is not apparent that there is one or more compound, or one or more classes of compounds that might be used to achieve the stimulation or inhibition of expression of a set of these polypeptides, as each polypeptide is presumably expressed as the product of a different gene, each of which is perhaps differently regulated by one or more uncommon factors.

Although one or more antibodies to which the claims of Group IV are directed include those that bind one or more of the polypeptides of which the "marker" of the claims of Group V, the nucleic acid molecules encoding those one or more polypeptides are patentably distinct from antibodies that bind to one or more of the same polypeptides. A nucleic acid molecule, or polynucleotide and an antibody are chemically distinct molecule because a polynucleotide is composed of polymers of nucleotides, whereas antibodies are composed of polymers of amino acids. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, the claimed polynucleotide does not encode a polypeptide chain of the claimed antibody; and the claimed antibody cannot be encoded by the claimed polynucleotide. Therefore, inventions of Group IV and V are patentably distinct products.

For all of the above reasons explaining why the different inventions of Groups I and IV-VII are patentably distinct products, searching the claims directed to more than one of these inventions would be unduly burdensome. The inventions have acquired a separate status in the arts, as evidenced by their separate classifications and/or the art recognized divergence of the claimed subject matter; and the search necessary to examine claims directed to any one of these groups of inventions is not the same, nor is it coextensive in nature and scope with that necessarily performed to examine claims

directed to any other. Therefore, having to search more than one of the inventions of Groups I and IV-VII would constitute a serious burden.

Since the products of the inventions of Group I and IV-VII are patentably distinct, each from the others, and because the examination of more than one could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The processes of the inventions of Groups I-III and VIII-XI are unrelated, or otherwise patentably distinct, each from the others, for the following reasons:

The processes of the inventions of Groups I, VIII, and X are methods for diagnosing pancreatic cancer, whereas the inventions of Group II are methods for identifying and/or obtaining a compound that *interacts with and/or inhibits the activity of one or more polypeptides*, the inventions of Group III are methods for identifying and/or obtaining a compound that *inhibits the expression of one or more polypeptides*, and the inventions of Groups IX and XI are methods for determining susceptibility to pancreatic cancer.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects. See MPEP §§ 806.04 and 808.01. In this instance, the specification does not appear to disclose that the inventions of Groups I, VIII, and/or X, the inventions of Group II, the inventions of Group III, and/or the inventions of Groups IX and XI are useable together. Therefore, because the inventions of Groups I, VIII, and/or X, the inventions of Group II, the inventions of Group III, and/or the inventions of Groups IX and XI have different purposes, as well as having different modes of operation, different functions, and different effects, the inventions appear unrelated.

If not unrelated, the processes of the inventions of Groups I-III and VIII-XI are patentably distinct, each from the others, for the following reasons:

Again, the inventions of Groups I, VIII, and/or X, the inventions of Group II, the inventions of Group III, and/or the inventions of Groups IX and XI have different purposes or objectives. In addition, although the inventions of Groups I and II, I, VIII, and X are each processes for diagnosing pancreatic cancer, they are materially different

processes comprising different process steps. For example, the inventions of Group I are processes comprising detecting the presence of, an amount of a "marker", which is described in the claims as comprising one or more specifically identified polypeptides; in contrast, the inventions of Group VIII are processes comprising detecting or measuring the amount of one or more polypeptides, as opposed to a "marker", which absent a showing otherwise, is presumed structurally distinct from a polypeptide. As explained above, it is not apparent what material constitutes the "marker" to which the claims are directed; it might however constitute a protein biochip comprised of one or more of the specified polypeptides, which are affixed in a particular pattern upon a suitable composite material. Thus, the nature and substance of the "marker" is regarded as distinct from one or more polypeptides, per se. Furthermore, while the inventions of Groups I and VIII comprise detecting such a "marker" and one or more polypeptides, respectively, the inventions of Group X are processes comprising detecting or measuring an amount of at least one nucleic acid molecule. The processes for detecting and quantifying proteins are markedly different from the processes for detecting and quantifying nucleic acid molecules. Similarly, although the inventions of Groups IX and X are processes for determining whether a subject is more or less susceptible to, or more or less likely to develop pancreatic cancer, the inventions of Group IX comprise detecting or quantifying at least one polypeptide, whereas the inventions of Group XI comprise detecting or quantifying at least one nucleic acid molecule. As explained, these processes are materially different and comprise different steps, but also, because the transcription and translation or post-translation processing of proteins is not often coordinately regulated, the processes are expected to have different criteria for success, as in particular, each measures a different endpoint, which is expected to correlate differently with a subject's susceptibility to the disease. As for the inventions of Groups II and III, these processes identify compounds having different effects, as the processes of Group II identify compounds that bind to and/or inhibit the activity of one or more polypeptides, whereas the processes of Group III identify compounds that inhibit the expression of one or more polypeptides. While the nature and substance of these different types of compounds is not specified in the claims, it is

presumed they may be as markedly different in both structure and function as they are in effect. As such, the processes of Groups II and III necessarily involve different process steps, or assays that measure different endpoints, and are thus expected to have different criteria for success. Because the claimed processes of the different groups have different purposes or objectives, and involve the measurement of different endpoints, the establishment of different correlations, and/or have different criteria for success, they are patentably distinct, each from the others.

Because any of the inventions of Groups I-III and VIII-XI are distinct for these reasons, the search required to examine claims directed to any one of these inventions is not the same, nor is it coextensive with the search required to examine claims directed to any other. Furthermore, the inventions of Groups I-III and VIII-XI have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter. Because different searches would have to be performed to examine claims directed to the inventions of Groups I-III and VIII-XI, an examination of more than one would constitute a serious burden.

Since the inventions of Groups I-III and VIII-XI have been shown to be patentably distinct, each from the others, and because the examination of more than one could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

5. This application contains claims 1-12 and 20-22 of Group I, which are directed to patentably distinct species of the claimed invention, wherein said "marker" is comprised

of one or more polypeptides selected from a group consisting of the polypeptide specifically identified in any of claims 1, 2, and 20-22.

Each species of these inventions is patentably distinct from the others since each involves detecting and/or quantifying a "marker", which comprises one or more different polypeptides, where each of said polypeptides is distinct from the others because each has a unique amino acid sequence that differs from the others. Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, because the search of any one "marker" comprised of one or more of the specified polypeptides will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one "marker" to which the claims of elected group of inventions will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If

claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. This application contains claims 13, 14, 33, and 34 of Group II, which are directed to patentably distinct species of the claimed invention, wherein said "compound" interacts and/or inhibits or antagonizes one or more polypeptides selected from a group consisting of the polypeptide specifically identified in any of claims 13, 14, and 33.

Each species of these inventions is patentably distinct from the others since each involves screening compounds to identify and/or obtain a "compound", which is capable of binding to, and/or inhibiting the activity of one or more different polypeptides, where each of said polypeptides is distinct from the others because each has a unique amino acid sequence and presumably functions differently from the others. Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, because the search of any one "compound" effective to bind to and/or inhibit the activity of one or more of the specified polypeptides will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one or more polypeptides to which the claims of elected group of inventions will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. This application contains claims 15 and 35 of Group III, which are directed to patentably distinct species of the claimed invention, wherein said "host" expresses one or more polypeptides, and said compound inhibits the expression of said one or more polypeptides, wherein said one or more polypeptides is/are selected from a group consisting of the polypeptide specifically identified in any of claims 15 and 35.

Each species of these inventions is patentably distinct from the others since each involves screening compounds to identify and/or obtain a "compound", which is capable of inhibiting the expression of one or more different polypeptides, which are each expressed in a host contacted with the compound, where each of said polypeptides is distinct from the others because each has a unique amino acid sequence and is encoded by a gene that differs from the genes encoding the others. Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, because the search of any one "host" expressing one or more of the specified polypeptides, the expression of which are inhibited by a compound, will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to

perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one or more polypeptides to which the claims of elected group of inventions will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. This application contains claims 16, 17, 36, and 37 of Group IV, which are directed to patentably distinct species of the claimed invention, wherein said "antibodies" include one or more antibodies that bind specifically to one or more polypeptides, wherein said one or more polypeptides is/are selected from a group consisting of the polypeptide specifically identified in any of claims 16 and 36.

Each species of these inventions is patentably distinct from the others since each is one or more antibodies, which is capable binding specifically one or more different polypeptides, where each of said polypeptides is distinct from the others because each has a unique amino acid sequence that differs from that of the others. Accordingly, the examination of claims directed to any one species of invention would require a unique

search that is not required for examination of any of the other species of invention, because the search of any one or more antibodies capable of binding specifically to one or more of the specified polypeptides will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one or more polypeptides to which the claimed antibodies must bind, to which species the claims of elected group of inventions will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. This application contains claims 18 and 38 of Group V, which are directed to patentably distinct species of the claimed invention, wherein said one or more nucleic acid molecules encoding a "marker", which is comprised of one or more polypeptides

selected from a group consisting of the polypeptide specifically identified in any of claims 1 and 20.

Each species of these inventions is patentably distinct from the others since each is a kit comprising one or more nucleic acid molecules encoding a "marker", which comprises one or more different polypeptides, where each of said polypeptides is distinct from the others because each has a unique amino acid sequence that differs from the others. Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, because the search of the nucleic acid molecules encoding any one "marker" comprised of one or more of the specified polypeptides will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one "marker", which is encoded by the one or more nucleic acid molecules, to which the claims of elected group of inventions will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. This application contains claims 18 and 38 and claims 19, 39 and 40 of Groups VI and VII, respectively, which are directed to patentably distinct species of the claimed invention, wherein said kit comprises one or more compounds that either activate or inhibit the activity of one or more polypeptides, or otherwise stimulate or inhibit the expression of one or more polypeptides, wherein said one or more polypeptides is/are selected from a group consisting of the polypeptide specifically identified in any of claims 19, 39 and 40.

Each species of these inventions is patentably distinct from the others since each is a kit comprising one or more compounds, which are capable of affecting either the activity or the expression of one or more different polypeptides, where each of said polypeptides is distinct from the others because each has a unique amino acid sequence, has a different activity, and is encoded by a gene that differs from the genes encoding the others. Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, because the search of any "one or more compounds" capable of affecting the activity or the expression of one or more of the specified polypeptides will not provide adequate information regarding any other "one or more compounds". Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one or more polypeptides, the activity or expression of which

is affected by the one or more compounds of which the kits are comprised, to which the claims of elected group of inventions will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. This application contains claims 23-26 directed to the inventions of Group VIII or IX, which are directed to patentably distinct species of the claimed inventions, wherein said method comprises detecting or quantifying one or more polypeptides selected from a group consisting of the polypeptide specifically identified in any of claims 23, 24, and 25.

Each species of these inventions is patentably distinct from the others since each involves detecting or quantifying one or more different polypeptides, where each of said polypeptides is distinct from the others because each has a unique amino acid sequence. Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, because the search of any one or more polypeptides will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it

coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of elected invention by identifying the one or more polypeptides to which the claims of elected group will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

12. This application contains claims 27-32 directed to the inventions of Group X or XI, which are directed to patentably distinct species of the claimed inventions, wherein said method comprises detecting or quantifying one or more nucleic acid molecules encoding a "marker", wherein said "marker" is in accord with the "marker" of claim 23.

As noted above, claim 23 does not define the "marker" to which claims 27-32 are directed. Nevertheless, in the interest of advancing prosecution it is presumed the "marker" might comprise one or more of the polypeptides disclosed in this application.

Accordingly, each species of these inventions would be deemed patentably distinct from the others since each involves detecting or quantifying one or more nucleic acid molecules encoding a "marker", which is comprised of any of the disclosed polypeptides, each of which is distinct from the others because each has a unique amino acid sequence. Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, because the search of one or more nucleic acid molecules encoding a "marker" comprised of any one or more polypeptides will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one or more polypeptides of which the "marker" is comprised, which is encoded by the one or more nucleic acid molecules to which the claims of elected group of inventions will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If

claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D., whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

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June 8, 2006